FEB 01 2002

K013971

I. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

510(k) Summary Of Safety and Effectiveness

I. General Information

This Summary of Safety and Effectiveness information is being submitted in accordance with the requirements of the SMDA of 1990 and 21 § 807.92

Establishment:

- Address: Becton Dickinson VACUTAINER Systems
  1 Becton Drive
  Franklin Lakes, NJ 07417-1885
- Registration Number: 2243072
- Contact Person: Keith M. Smith
  Director, Regulatory Affairs
  Telephone No.:(201) 847-5837
  Fax No. (201) 847-7040
- Date of Summary: September 28, 2001

Device

- Trade Name: BD Vacutainer™ Safety Coagulation tube
- Classification Name: Tubes, Vials, Systems, Serum Separators, Blood Collection
- Classification: Class II
- Performance Standards: None Established under 514 of the Food, Drug and Cosmetic Act

II. Safety and Effectiveness Information Supporting the Substantial Equivalence Determination

Substantial Equivalence Declaration:

The term "Substantial Equivalence" as used in this 510(k) Premarket Notification is limited to the definition of Substantial Equivalence found in the Federal Food, Drug, and Cosmetic Act, as amended and as applied under 21 CFR § 807, Subpart E, under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of, substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

- Device Description:

  The BD Vacutainer™ Safety Coagulation tubes are sterile, plastic, evacuated blood collection tubes. The tubes contain 0.109M or 0.129M Sodium Citrate as an anticoagulant intended to prevent whole blood from clotting prior to analysis. The specimen is centrifuged and the plasma portion is analyzed for coagulation parameters to detect clotting time disorders and to monitor patients undergoing anticoagulation therapy. The benefits of a plastic tube decrease the occurrence of accidental breakage, increases the safety of laboratory personnel and reduces the necessity of repeat specimens.

- Intended Use:

  The BD Vacutainer™ Safety Coagulation tube is an evacuated blood collection tube that provides a means of collecting, transporting and processing blood in a closed tube. The buffered sodium citrate additive provides an anticoagulated specimen that may be used for clinical laboratory coagulation assays. The benefits of a safety plastic coagulation tube with Hemogard Safety Closure Assembly are:

  - reduced risk of specimen tube breakage
  - reduced exposure to blood by laboratory personnel and to minimize blood splatter during stopper removal

  These benefits lead to increased safety of laboratory personnel and reduced necessity of repeat specimen collection.

- Synopsis of Test Methods and Results

  Clinical evaluations were performed to determine the safety and efficacy of the BD Vacutainer™ Safety Coagulation tube. The BD Vacutainer™ Safety Coagulation tube (plastic) was compared to the currently marketed VACUTAINER™ Brand Sodium Citrate Tube (glass). The results of the

clinical evaluation demonstrated that the BD Vacutainer™ Safety Coagulation tube provides clinically equivalent results when compared to the VACUTAINER™ Brand Sodium Citrate Tube for Normal, Warfarin, Heparin and other patient donors.

- Substantial Equivalence

Based on comparison of the device features, materials, and intended use, the BD Vacutainer™ Safety Coagulation tube can be shown to be substantially equivalent to the commercially available predicate device.

The predicate device, K number, and clearance date are identified below:

Manufacturer	Predicate Device	K-Number	Clearance Date
Becton Dickinson VACUTAINER™ Systems	VACUTAINER™ Brand Sodium Citrate Tube	N/A	Pre-Amendment Device and, therefore, exempt from premarket notification requirements according to the MDA of 1976

Keith M. Smith
Director, Regulatory Affairs

11/30/01
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 01 2002

Mr. Keith M. Smith
Associate Director, Regulatory Affairs
BD Pharmaceutical Systems
Becton Dickinson and Company
1 Becton Drive
Mail Code 440
Franklin Lakes, New Jersey 07417-1880

Re: k013971
Trade/Device Name: BD Vacutainer™ Safety Coagulation Tube
Regulation Number: 21 CFR § 862.1675
Regulation Name: Tubes, Vials, Systems, Serum Separators, Blood Collection
Regulatory Class: II
Product Code: GIM
Dated: November 28, 2001
Received: December 3, 2001

Dear Mr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

B. INDICATIONS FOR USE

510(k) Number (if known): K013971

Device Name: BD Vacutainer™ Safety Coagulation tube

Indications for Use:

The BD Vacutainer™ Safety Coagulation tube is a plastic evacuated blood collection tube that provides a means of collecting, transporting and processing blood in a closed tube. The buffered sodium citrate additive provides an anticoagulated specimen that may be used for clinical laboratory coagulation assays. The benefits of a safety plastic coagulation tube with Hemogard Safety Closure Assembly are:

- reduced risk of specimen tube breakage
- reduced exposure to blood by laboratory personnel and to minimize blood splatter during stopper removal

These benefits lead to increased safety of laboratory personnel and reduced necessity of repeat specimen collection.

(Division Sign-Off)
Division of Clinical Laboratory Devices

(Please do not Write below this line-continue on another page if needed)

510(k) Number K013971

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Or Over-the-Counter Use _____

(Per 21 CFR § 801.109) (Optional format 1-2-96)